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foundation
Benefitting people and society

Guidelines for applicants

INVESTIGATOR INITIATED CLINICAL TRIALS 2024

Facts about the call

Total amount available for granting:
DKK 80 million

Amount available per grant:
From **DKK 5 to 20 million per grant** over a project period of 3-5 years

Call opens:
June 20, 2024

Call closes:
August 21, 2024 (14:00 CEST)

Applicant notification:
Mid December 2024

Earliest start date:
January 1, 2025

Latest start date:
November 30, 2025

IMPORTANT!
The grant cannot be started/activated until all approvals from the relevant public authorities have been obtained

Review committee:
The Committee on Clinical and Translational Medicine

Contact:

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All Grant Recipients must comply with the 'General Terms and Conditions' for grants from the Novo Nordisk Foundation (the Foundation).

The Foundation will treat all applicant and application information confidentially. Read more about how the Foundation processes personal data under 'privacy & security' in the online application system, NORMA. See how to access NORMA in section 2 of these guidelines.

You can find more information about the Foundation's application and granting process at the NORMA Help Centre. Detailed information about the different parts of the application is available in NORMA.

1 Investigator Initiated Clinical Trials 2024

1.1 Purpose

The purpose is to strengthen the opportunities to carry out larger clinical trials in Denmark that **do not** have a direct industrial and/or commercial purpose. The ultimate objective is to improve the treatment of patients through new medicine and new technology and to ensure the highest quality in treatment.

Grants are available for both monocentric and multicenter national trials. If applying for a multicenter international clinical trial, the coordinating **investigator (main applicant) and the trial must be anchored in Denmark.** For international studies anchored outside Denmark, the grant can be applied for to cover only the part of the project carried out in Denmark, and in this case, it is important that the main applicant, who must be anchored in Denmark, has a key role in the clinical trials.

1.2 Areas of support

Applications may be submitted for most types of larger clinical trials that include patients and aim to improve existing treatment routines (product development, analysis and follow-up are not considered a clinical trial). Randomized controlled trials are preferred; however, nonrandomized trials are also accepted. Examples include, but are not limited to:

- the use of medicines (including repositioning)
- medical technology (including testing medical devices)
- treatments such as surgical procedures, radiotherapy and new advanced genetic and cell therapy methods
  therapies such as physiotherapy or other intervention or rehabilitation initiatives

  The Programme supports investigator initiated clinical trials and projects aimed solely at discovery, product development or implementation **will not be considered**.

1.3 Eligibility

Clinical trials with an industrial and/or commercial purpose **will not be considered**!

Project:

- The clinical trials must conform to good clinical practice guidelines (GCP).
- Clinical relevance and scientific quality is imperative, and a detailed protocol including calculation of power, data management plan, and plan for statistical analysis of data must be included.
- All clinical trials that receive a grant from the Novo Nordisk Foundation **must be registered** at ClinicalTrials.gov or Clinical Trials Information System (CTIS) before starting/activating the grant.
- In case of industry sponsored material(s) there **must be a written agreement** (before application deadline) between the researcher and the industrial partner ensuring the researcher full ownership of obtained data and the rights to publish independently of the industry sponsor.
- When the clinical trial ends, the anonymized data **must be made available** to other researchers through public databases such as the Zenodo open data repository (CERN) or other equivalent databases.
- If an application for the clinical trial previously has been unsuccessfully applied for at the Novo Nordisk Foundation, it is imperative that it is described how the application has been improved since last submitting the proposal.
- An applicant can submit an application to the foundation before all legal approvals have been obtained, but the grant **cannot be activated** until all approvals from the relevant public authorities have been obtained. If a grant is not activated within one year following the date of the grant letter, the grant will be considered annulled.

Main applicant:

- The main applicant (investigator) must have a MD and must be a specialist physician. Main applicant must be employed at the hospital in Denmark where the project is anchored, and he/she **must be a clear driver/PI of the trial.**
- The main applicant must have documented experience in research leadership and well-documented research activities.
- The main applicant is responsible for the project and for scientific and financial reporting.
- Researchers who already hold an active grant within 'Investigator Initiated Clinical Trials' from the Novo Nordisk Foundation, as main applicant, are eligible to apply for a new grant during the final year of the existing grant. The grant period for the new grant cannot overlap the active grant. They can, however, be co-applicants on new projects/applications.
- Employees on the project (**including postdocs and PhD students) cannot be co-applicants.**

Sponsor:

- A sponsor is the institutional head of the department who assumes responsibility for initiating and leading a clinical trial (**cannot be the main applicant**).
- The institution at which the main applicant is anchored must take responsibility as a sponsor of the clinical trial. The sponsor has overall responsibility for the quality of the clinical trial and for ensuring that the clinical trial is conducted in accordance with Good Clinical Practice.
- The sponsor, together with the main applicant, must ensure that all the necessary permits are obtained and that all the relevant public authorities are notified.
- The sponsor must also take responsibility for administering the grant.

- A letter, signed by the institutional head, stating the role as sponsor for the trial, and administrative responsibility of the grant **must be uploaded** to the application (under 'uploads').

Co-applicant:

- The main applicant may have up to four named co-applicants. Co-applicants take an active part in organizing and implementing the project and will receive a share of the grant. The application must clearly describe the co-applicants' part in the project and their share of the budget.
- For each co-applicant, a short CV must be included in the application (one PDF file per co-applicant should be uploaded under 'co-applicants').
- Employees on the project (**including postdocs and PhD students) cannot be co-applicants.**

IMPORTANT RULES!

- An applicant may submit only one application to the Novo Nordisk Foundation for an "Investigator Initiated Clinical Trials grant". If an applicant submits more than one "Investigator Initiated Clinical Trials grant" application for simultaneously review, only the first application submitted will be evaluated, while the subsequent applications will receive administrative rejections.
- An applicant that holds an active "Investigator Initiated Clinical Trials grant" from the Novo Nordisk Foundation is only eligible to apply for a new "Investigator Initiated Clinical Trials grant" during the final year of the existing grant, and the two grant periods cannot overlap.
- While a project submitted to one call in the Novo Nordisk Foundation is under evaluation – a similar or overlapping project CANNOT be submitted to other calls from the Novo Nordisk Foundation. I.e., projects submitted for Distinguished Investigator grants cannot be submitted to any other calls in the Novo Nordisk Foundation until the outcome of this call has been published.
- It is permitted to hold two or more active grants of different types ('project', 'collaboration', 'challenge' and 'personal investigator'), i.e., researchers with an active grant of a specific type may apply for a new grant of a different type.

1.4 Funding

A total of up to DKK 80 million is available for grants between DKK 5 million and DKK 20 million for projects lasting up to 3-5 years.

Applicants may apply for funding for the following types of expenses directly related to the project:

- Salary for a temporary employee who will carry out the clinical responsibilities of the main applicant during the project period (up to 50%).
- Salary for research and technical assistance, including postdoctoral researchers, PhD students (incl. tuition fee up to DKK 80,000 per budget year), technicians and research-year students.
- Operating expenses, e.g. lab consumables, chemicals and reagents, research animals, sequencing/proteomics and other analysis services directly related to the project.
- Equipment required for the project, however not exceeding 20% of the budget total.

- Travel expenses in relation to the project, i.e. conference and workshop participation and presentation of research results, up to DKK 50,000 per budget year.
- Other travel expenses directly related to the project, i.e. experiments carried out in other labs for a limited period.
- Publication of results emanating from the research project, up to DKK 50,000 per budget year.
- Bench fee (must be specified in the budget if applying for this post).
- Administrative expenses (must be specified in the budget if applying for this post).

Full-time equivalents (FTEs)
For each salary entry, please specify the FTE in years within the designated FTE field. This will indicate the proportion of a full-time position that the project funding will support for each year of the grant period. One full-time employee for one year equals 1.0 FTE.

Bench fee (not applicable to Danish universities) [delete if not relevant]
Bench fee can be included in the budget for support of individual researchers to cover expenses needed to conduct the proposed research.

Bench fee is calculated per academic employee actively working on the project [eligible to apply for salary]. It may only be used for expenses related to the research project which cannot be included within another individual budget category. Bench fee may account for a maximum of DKK 8,000 per month per FTE. The budget must specify the expenses covered by the bench fee, which may include:

- Common or shared laboratory expenses and consumables
- Laboratory utilities (electricity, gas, water)
- Maintenance of essential equipment
- Service contracts
- Technical and IT support

PLEASE NOTE that bench fee cannot cover rent, administrative support, representation, social contributions etc. A valid bench fee policy in line with the Foundation's requirements must be available at the time of application, and this official documentation from the administrating/co-applicant's institution must be provided upon request.

Project supplement for research grants: (Danish universities only) [include if administrating institutions can be Danish universities]
The project supplement contributes to the coverage of indirect costs at Danish universities, and replaces budget posts such as administrative costs, bench fee and parental leave.

More information on the joint model for project supplement is found at Universities Denmark's website. Questions related to the project supplement should be directed to the research support units at your university.

Administrative support (not applicable to Danish universities)

Administrative support may account for a maximum of 5% of the total budget and must be included therein. The administrative support:

- can cover expenses such as for accounting, payment of salaries, purchasing, hiring, as well as auditing and financial reporting on the project
- cannot cover administrative expenses that are not directly related to the project
- can via the host institution be shared between the institutions of the main- and co-applicant(s), as detailed in the application budget
- is not automatically included in the grant and must be stated/applied for in the application budget but should not be specified in detail

The Foundation will not award funding for:

- Commercial activities
- Overhead/indirect costs (such as rent, electricity, water and maintenance)
- Clinical trials with a direct industrial and/or commercial purpose
- Industry-initiated clinical trials, as well as drug testing derived from industry
- Double funding of projects:
- If the applicant has received funding for the proposed project from other sources, in part or in full, this must be accounted for in the budget, as no budgetary overlaps are allowed
- If an identical or overlapping project proposal has been submitted to other funding institutions than the Foundation, it must be noted in the application
- If the applicant receives funding for the project, or parts of the project, from other sources following submission of the application to the Foundation, the Foundation must be informed immediately

1.5 Language

The application and all additional materials must be submitted in English. The language chosen will not influence the assessment of the application.

1.6 Application process

When all applications have been assessed, applicants will be notified about whether they have been awarded a grant. The notification e-mail will be sent from norma-noreply@novo.dk to the e-mail address used when creating a profile in NORMA.

PLEASE NOTE: The Foundation does not provide feedback in case an application is declined.

1.7 Assessment criteria

NNF's Committee on Clinical and Translational Medicine will primarily assess the application based on the following criteria:

Quality, novelty, feasibility, clinical relevance of the project and the contributions and merits of the both the main- and the co-applicants.

If you have an active grant from the Foundation, this may be taken into consideration in the evaluation of your application for a new grant. In general, it is recommended that the main applicant has delivered results on the active grant(s) before submission of a new application to the Foundation.
If you apply while having an active grant from the Foundation, you must describe how the project you propose in this application is different from and/or coherent with the project(s) already funded and briefly describe the progress of the already funded project(s). This information should be included in the **Project Description**.

2 The application and grant management system NORMA

2.1 Creating and submitting an application

The Foundation uses the application and grant management system NORMA: https://norma.novonordiskfonden.dk

If you do not have a user profile in NORMA, you can create one by clicking **Register** on the login page. The main applicant should only have one user profile. Please use your work e-mail address for registration.

The registered user who submits an application will be legally responsible for the truthfulness of the content of the application.

You can find guidance on how to create and submit an application at: NORMA Help Centre.

If you experience technical problems and cannot find a solution in the NORMA Help Centre, please contact NORMA Support: norma-support@novo.dk.

3 Application content

This section provides guidelines on the content required in the sections of the online application form for this call. Detailed information about the different parts of the application is available in NORMA.

3.1 Applicant

The **Applicant** tab pertains to information about all those involved in an application, meaning the main applicant or contact person applying on behalf of an organisation/institution as well as any co-applicants.

3.2 Co-applicant(s)

For this call, up to four (4) co-applicants are allowed for the application.

It is possible to be co-applicant on more than one application per application round. **However**, if a person is co-applicant on more than one application, the overall workload and commitment of the co-applicant may be taken into consideration in the evaluation of the application(s).

Co-applicants are expected to actively participate in organising and implementing the project and should, consequently, be allocated a share of the grant. The project description should clearly describe the role of all co-applicants, and the budget should clearly indicate the co-applicants' allocation of the total budget. Co-applicants must be invited through NORMA and subsequently enter their details in the system. Please follow the instructions in NORMA on how to invite co-applicants to your application.

Please note that co-applicants can read, edit and upload information into the application portal, **but only the main applicant is able to submit the final application.**

Inviting co-applicants can be time-consuming.
Please invite any co-applicant(s) as soon as possible and well in advance of the submission deadline.

3.3 Institution

Please provide information about the institution where the grant will be administered. This institution is where the main applicant will be employed during the grant period, and the institution that will ultimately be responsible for administering and allocating the grant, including budgeting, financial reporting and staff supported by the grant.

It can take up to five working days to register a new administrating institution in NORMA.
The application cannot be submitted before the institution has been registered.

3.4 Proposal

Describe the project using the fields in the **Proposal** tab.

PROJECT TITLE
Please provide a short title for the project (maximum 150 characters, including spaces, line breaks and special characters).

BRIEF PROJECT DESCRIPTION
Please provide a brief stand-alone summary of the project describing its purpose, target group and activities (maximum 2,000 characters, including spaces, line breaks and special characters).

PROJECT DESCRIPTION
Project description can be a maximum of 30,000 characters (including spaces, line breaks and special characters).

The project description should include:

- The purpose, procedure, patient selection and randomization.

- A brief review of the existing knowledge in the field, including a review of existing treatment methods and their effectiveness and side effects.
- A summary of the expected improvements that the clinical trial aims to achieve.
- A clear protocol and the calculation of statistical power.
- A data management plan.
- A plan for statistical analysis of the data.
- A plan for sharing the data with other researchers after the clinical trial ends.
- A report on the permits obtained from public authorities at the time of application.
- A list of abbreviations used in the project description.

It must be clear from the project description how the project collaboration is ensured, and the work is distributed between the main- and the co-applicants. The project can also be a clearly defined (and not yet funded) part of a larger, running project, but in this case, it must be clearly described in the application.

Abbreviations should be defined at the first use, and preferably a list of abbreviations should be included in the project description.

ILLUSTRATION UPLOADS
A maximum of four illustrations can be uploaded here.

The following file formats for illustrations are accepted in the system: JPG, JPEG, PNG and BMP. The maximum accepted size for each illustration is 50 MB and 1050*1650 pixels.

LITERATURE REFERENCES
Please provide the reference information for the literature cited in the project description (maximum 8,000 characters, including spaces, line breaks and special characters).

LAY PROJECT DESCRIPTION
Please provide a brief summary for non-experts in lay language. If the application is awarded a grant, the text may be used for publication (maximum 1,000 characters, including spaces, line breaks and special characters).

PUBLICATION LISTS
(for main applicant): can be a maximum of 5,000 characters (including spaces, line breaks and special characters). When providing the list of 10 publications for main applicant in the application scheme, please include the full author list, with own name **bolded**, and avoid the used of *et al*. Please consider making the main applicant's full list of publications available for the reviewers via ORCID.

CVs
Can be maximum 4,000 characters for the main applicant (including spaces, line breaks and special characters).

CV for co-applicant must be uploaded (see section 3.2). Please include in all the CVs a short bibliographic overview summarizing total number of peer-reviewed publications, number of first authorships, number of corresponding authorships, number of citations and H-index. Please also include in the CVs an overview of current grants and indicate how much research time (in %) is committed to each of the projects.

3.5 Budget

Enter the project grant period, and the budget template will become available.
Only budget information submitted via the **Budget** tab will be considered in the review process. Any additional budget information attached under **Appendices** (or any other tabs) will not be considered.

3.6 Appendices

All uploads must be in PDF format. NORMA automatically places these uploads at the end of the application. Appendices other than those specified here are not permitted and will not be included in the evaluation.

Mandatory uploads:

1) CV for co-applicants (maximum of two (2) pages per co-applicant), must be filled out under 'co-applicants uploads' - **not under** 'other uploads'.
2) A signed letter from the institution taking responsibility for sponsoring the project and administrating the grant, must be uploaded under 'sponsor letters'.